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K001141

Allegiance

XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
POWDER-FREE STERILE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM

Manufacturer:	Allegiance Healthcare Sdn. Bhd. Plot 87 Kampung Jawa Bayan Lepas Penang, West Malaysia 11900
Regulatory Affairs Contact:	Erica Sethi 1500 Waukegan Road, Bldg. WM McGaw Park, IL 60085
Telephone:	(847) 785-3337
Date Summary Prepared:	March 21, 2000
Common Name:	Patient Examination Glove
Classification:	Glove, Examination (Latex)
Predicate Devices:	Flexam Powder-Free Latex Examination Gloves With Protein Labeling Claim
Description:	Powder Free Sterile Examination Gloves With Protein Labeling Claim are formulated using latex and offered sterile in sizes Small, Medium and Large.
Intended Use:	Powder-Free Sterile Latex Examination Gloves With Protein Labeling Claim are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

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XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't) POWDER-FREE STERILE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM

Substantial Equivalence	Powder Free Sterile Examination Gloves With Protein Labeling Claim are substantially equivalent to Flexam Powder-Free Latex Examination Gloves in that they provide the following characteristics: - intended use - size, design, product features - made of natural rubber latex - physical characteristics

Summary of Testing:

Test	Result
Primary Skin Irritation	Glove does not display irritation potential.
Guinea Pig Maximization	Glove does not display sensitization potential.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber examination gloves per ASTM D3578-99.
Barrier Defects	Glove meets or exceeds requirements per 21 CFR §800.20 and ASTM D3578-99, AQL=2.5.
Powder Level	Glove meets powder level requirements for "Powder Free" designation per ASTM D 3578-99.
Protein Labeling Claim	Glove meets requirements for protein claim of 50 microgram or less of total water extractable protein per gram of glove using the ASTM Lowry test method (ASTM 5712-95).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

Ms. Erica Sethi
Allegiance Healthcare Corporation
1500 Waukegan Road
William Merz Building
McGaw Park, Illinois 60085

Re: K001141
Trade Name: Powder-Free Sterile Latex Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: March 22, 2000
Received: April 10, 2000

Dear Ms. Sethi

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

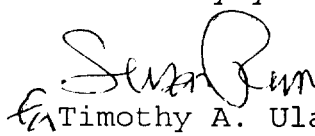
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

Applicant: Allegiance Healthcare Corporation

510(k) Number: K001141

Device Name: Powder-Free Sterile Latex Examination Gloves With Protein Labeling Claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001141